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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/749,387	01/02/2004	Naoyuki Fukuchi	246515US0DIV	9339

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EXAMINER

LIU, SAMUEL W

ART UNIT PAPER NUMBER

1653

DATE MAILED: 05/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/749,387

Applicant(s)

FUKUCHI ET AL.

Examiner

Samuel W. Liu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 1/2/04 & 4/19/05.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11, 21-23 and 25-34 is/are pending in the application.
- 4a) Of the above claim(s) 21-23 and 25-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☒ Certified copies of the priority documents have been received in Application No. 09/969,763.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of claims

Claims 1-11, 21-23 and 25-34 are pending.

The preliminary amendment filed 1/2/04, which amends claims 1-11, 21-23 and 25-34, cancels claims 12-20 and 24, and adds claims 25-34 has been entered.

Election/Restrictions

Applicant's election (filed 4/19/05) with traverse of Group I, claims 1-11, is acknowledged. The traversal is on the ground that Groups III-V are narrower in scope than the claims of Group II, i.e., Group II should embrace the claims of Groups III-V (see page 2). The applicants' argument is found to be not persuasive because, as stated in the Office action mailed 3/25/05, Groups II-V are drawn to distinct/different structures of polynucleotide, each directed to distinct mutation(s) (i.e., structural alteration(s)); e.g., the Group V polynucleotide encoding a mutant protein characterized by substitution of any acidic amino acid residues which C α existing within 10 Å distance from C α of amino acid residue 103, whereas the polynucleotides of Groups II-IV do not acquire such the structural characteristic. The restriction requirement is therefore still deemed proper and is therefore made FINAL.

Claims 21-23 and 25-34 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. Hence, the elected claims 1-11 are under examination to the extent that they are drawn to the elected invention.

Claims/specification Objections

The disclosure is objected to because of the following informalities:

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In claim 1, after “secondary or tertiary structure composed of” should add “(*from N-terminus to C-terminus*)” so as to the structural components followed by “*composed of*” is sequential thereof.

In claim 4, “amino acid numbers” should be changed to “amino acid residues”. See also claims 5-6

On paragraph [0023], “amino acid numbers” should be changed to “amino acid residues”. The same changes should be made throughout the specification.

Appropriate correction is required.

IDS

The references listed in the IDS filed 1/2/04 have been considered by Examiner.

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter that the applicant regards as his invention.

Claims 1-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites “...form a secondary or tertiary structure”; the term “or” in the recitation renders the claim indefinite because the claim as written ambiguously encompasses (i) a folded (functional) protein and (ii) a partially unfolded (non-functional) protein. Note that the partially unfolded protein can comprise all the secondary structures of a protein (see page 157 of Dong, A. et al. reference, *Arch. Biochem. Biophys.*, (2005) Vol. 436, pages 154-160). Thus, claim 1 should make it clear that the protein produced is biologically active, i.e., fully folded, or non-

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active, i.e., absent being ternary structure despite the presence of the secondary structures. See also claim 7. Claim 1 recites “homology of ...”; the recitation is unclear as to whether or not said “homology” refers to sequence *similarity* (based on structural motif(s) or consensus sequence or conservative amino acids), or, sequence identity. Note that homology is a qualitative not quantitative term. The dependent claims are also rejected.

Claim 9 does not make it clear that whether or not “bonding a polyoxyalkylpolyol group to the protein” refers to covalently conjugate said group to the protein or bonding via a non-covalent interaction. The dependent claims are also rejected.

Prior Art

The prior art made of record and not currently relied upon in any rejections is considered pertinent to Applicants’ disclosure:

Mizuno, H. et al. (*J. Mol. Biol.* (1999) 289, 103-112) teach a process of making and isolating coagulation factor IX-binding protein (IX-bp), which has anti-thrombotic activity and which has same folding pattern as the polypeptide of the instant SEQ ID NO:1 and at least 30% sequence identity to SEQ ID NO:3 thereof. Also, Mizuno et al. show a topological alignment of primary structures (i.e., amino acid sequence) with secondary structures thereof (see Figure 4). Further, Mizuno et al. teach conservative motifs (subsequences) of the protein IX-bp essential for biological functions, e.g., calcium binding, ligand recognition and stabilizing dimer of the protein thereof. The Mizuno’s reference provides information for further engineering the protein having anti-thrombotic activity.

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Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu whose telephone number is 571-272-0949. The examiner can normally be reached from 9:00 a.m. to 5:00 p.m. on weekdays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber, can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703 308-4242 or 703 872-9306 (official) or 703 872-9307 (after final). Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 305-4700.



Samuel W. Liu, Ph.D.
Art Unit 1653, Examiner
May 3, 2005



KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER